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10/779,993	02/17/2004	James D. Lewis JR.	HT-5755 DIV	1329
29200 7590 01/08/2008 BAXTER HEALTHCARE CORPORATION 1 BAXTER PARKWAY DF2-2E DEERFIELD, IL 60015			EXAMINER MOHANDESI, JILA M	
			ART UNIT 3728	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/779,993
Filing Date: February 17, 2004
Appellant(s): LEWIS ET AL.

MAILED

JAN 08 2008

Group 3700

Robert M. Barrett
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10/11/2007 appealing from the Office action mailed 07/24/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,692,361	JOHNSTON ET AL.	9-1987
4,936,456	BELL ET AL.	6-1990
4,910,147	BACEHOWSKI ET AL.	3-1990

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-7, 11-12, 22, 25 and 28-33 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston et al. (4,692,361). Johnston '361 discloses a container for holding products to be maintained and removed under sterile conditions, comprising: a flexible polymeric film formed into a bag having a cavity enclosed by a first wall, an opposing second wall, permanent seals about a periphery of the first and second walls, the seals joining an interior portion of the opposing first and second walls and creating a fluid-tight chamber within the cavity of the container and a fitment (see column 6, lines 57-61). See Figures 1 and 2 embodiments and column 1, lines 11-21. Johnston '361 discloses that the flexible containers are utilized in medical industry for containing, inter alias, parenteral solutions, dialysis solutions, frozen drugs and plasma. Regarding the actual product or composition (concentration of at least 20% albumin), the actual composition is merely a matter of user preference and entirely obvious to use whatever composition as desired. The flexible polymeric bag of Johnston '361 is capable of holding concentration of at least 20% albumin. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to store albumin concentrations in the flexible polymeric bag of Johnston '361, since the bag of Johnston '361 is suitable and utilized in the medical industry for containing, inter alias, parenteral solutions, dialysis solutions, frozen drugs and plasma (which contains albumin).

It is noted that, in the seal area where the fitment/fill tube is heat sealed to the outside layer of the flexible bag the seal area will be free of albumin concentration (since this seal is formed prior to filling of the flexible bag with albumin) and a permanent heat seal is formed around the fitment/fill tube area, see column 6, lines 57-61 and Figure 2 embodiment.

With respect to claims 11 and 12, see Figure 1 embodiment and column 3, lines 37-49. With respect to claim 29, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

The limitation under Official Notice is now taken as admitted prior art, therefore, with respect to claim 2, it would have been obvious to one of ordinary skill in the art at the time the invention was made in view of the admitted prior art to mix albumin with sterilized water and stabilizers.

With respect to claims 28 and 32 and the strength of the seal, this would be a design choice depending on the strength desired and cost of manufacturing.

Claims 8 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Johnston '361 as applied to claims 1 and 3 above, and further in view of Bacehowski et al. (4,910,147). Johnston '361 as described above discloses all the limitations of the claims except for the flexible bag further comprising an aperture adjacent an edge opposing the fitment. Bacehowski '147 discloses a flexible bag with an aperture adjacent an edge opposing the fitment to facilitate hanging of the flexible bag. Therefore, it would have been obvious to one of ordinary skill in the art at the time

the invention was made to provide an aperture adjacent an edge opposing the fitment of the flexible bag of Johnston '361 as taught by Bacehowski '147 to facilitate hanging of the flexible bag.

Claims 9-10 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston '361 as applied to claims 1, 3 and 5 above, and further in view of Bell et al. (4,936,456). Johnston '361 as modified above discloses all the limitation of the claims except for it is silent about the type of seal being used. Bell '456 discloses that chevron seals can be used instead of linear seals for closing the edges of a flexible bag. As a result of the chevron seal construction, relatively long tabs are formed to facilitate opening through stripping of the gussets from the bag. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide chevron seals in the flexible bag of Johnston '361 as taught by Bell '456 to facilitate opening through stripping of the gussets from the bag.

(10) Response to Argument

Contrary to Appellant's argument the seal area where the fitment/fill tube is heat sealed to the outside layer of the flexible bag the seal area will be free of albumin concentration (since this seal is formed prior to filling of the flexible bag with albumin) and a permanent heat seal is formed around the fitment/fill tube area, see column 6, lines 57-61 and Figure 2 embodiment.

Contrary to Appellant's argument the flexible bag of Johnston'361 is suitable for storing Albumin, since the flexible bag of Johnston '361 is suitable and utilized in the medical industry for containing, inter alias, parenteral solutions, dialysis solutions,

frozen drugs and plasma (which contains albumin). Furthermore appellant has not shown any convincing showing as why the flexible polymeric bag of Johnson is not capable of holding the albumin concentration of at least about 20% and how the bag of Johnson made of flexible polymeric film is different than the flexible polymeric film bag of the instant invention.

The claim would have been obvious because the substitution of one known element (plasma for albumin) for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

When a patent claims a structure already known in the prior art that is altered by the mere substitution of one element (plasma for albumin) for another known in the field, the combination must do more than yield a predictable result.

The claim would have been obvious because "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

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(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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January 07, 2008